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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,853	02/26/2002	Ron T. Shigeta JR.	3385.1	4537

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AFFYMETRIX, INC
ATTN: CHIEF IP COUNSEL, LEGAL DEPT.
3380 CENTRAL EXPRESSWAY
SANTA CLARA, CA 95051

EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,853	SHIGETA ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20 and 47, drawn to a method of producing a polypeptide, isolated polynucleotide comprising **SEQ ID NO: 1**, host cells, and gene delivery vehicle comprising same, classified in class 435, subclass 69.1, for example.

II. Claims 21, 22 and 48, drawn to and isolated polypeptide comprising **SEQ ID NO: 2** and pharmaceutical compositions comprising same, classified in class 530, subclass 350, for example.

III. Claims 23-26, drawn to an **antibody and a hybridoma cell** that produces it, classified in class 435, subclass 326, for example.

IV. Claims 27-30 (each in part), drawn to a method for identifying a modulator of a growth factor encoded by SEQ ID NO: 1 wherein the candidate modulator is an **antisense oligonucleotide**, classified in class 536, subclass 24.5, for example.

V. Claim s 27-30 (each in part), drawn to a method for identifying a modulator of a growth factor encoded by SEQ ID NO: 1 wherein the candidate modulator is a **ribozymes or a ribozymes derivative**, classified in class 536, subclass 24.5, for example.

VI. Claims 27-30 (each in part), drawn to a method for identifying a modulator of a growth factor encoded by SEQ ID NO: 1 wherein the candidate modulator is an **antibody**, classified in class 435, subclass 7.1, for example.

VII. Claims 27-30 (each in part), drawn to a method for identifying a modulator of a growth factor encoded by SEQ ID NO: 1 wherein the candidate modulator is an **liposome**, classification dependent upon agent structure.

VIII. Claims 27-30 (each in part), drawn to a method for identifying a modulator of a growth factor encoded by SEQ ID NO: 1 wherein the candidate modulator is an **small molecule**, classification dependent upon agent structure.

IX. Claims 27-30 (each in part), drawn to a method for identifying a modulator of a growth factor encoded by SEQ ID NO: 1 wherein the candidate modulator is an **inorganic compound**, classification dependent upon agent structure.

X. Claim 31, drawn to a **modulator**, classification dependent upon agent structure.

XI. Claims 32-35, drawn to a method for identifying a **receptor** for the growth factor encoded by SEQ ID NO: 1, classification dependent upon agent structure.

XII. Claim 36, drawn to a **receptor**, classified in class 530, subclass 300, for example.

XIII. Claims 37 and 38 (each in part), drawn to a method of diagnosing a pathogenic condition or susceptibility to a pathogenic condition that is associated with a genetic alteration in the growth factor encoded by SEQ ID NO: 1 wherein the genetic alteration is determined in the **polypeptide**, classification dependent upon how the genetic alteration is determined.

XIV. Claims 37 and 38 (each in part), drawn to a method of diagnosing a pathogenic condition or susceptibility to a pathogenic condition that is associated with a genetic alteration in the growth factor encoded by SEQ ID NO: 1 wherein the

genetic alteration is determined in the **nucleic acid**, classification dependent upon how the genetic alteration is determined.

XV. Claims 39-45, drawn to a **computer readable medium**, classified in class D14, subclass 300, for example.

XVI. Claim 46, drawn to a **transgenic animal**, classified in class 800, subclass 2, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, IV, V, VI, VII, VIII, IX, XI, XIII, AND XIV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of **recombinant production** of a polypeptide, which is not required by any of the other Inventions. Invention IV requires search and consideration of **antisense oligonucleotides**, which is not required by any of the other Inventions. Invention V requires search and consideration of **ribozymes**, which is not required by any of the other Inventions. Invention VI requires search and consideration of **antibodies as modulators**, which is not required by any of the other Inventions. Invention VII requires search and consideration of **liposomes**, which is not required by any of the other Inventions. Invention VIII requires search and consideration of **small molecules**, which is not required by any of the other Inventions. Invention IX requires search and consideration of **inorganic compounds**,

which is not required by any of the other Inventions. Invention XI requires search and consideration of **receptors**, which is not required by any of the other Inventions. Invention XIII requires search and consideration of **genetic alterations in a polypeptide**, which is not required by any of the other Inventions. Invention XIV requires search and consideration of **genetic alterations in a nucleic acid**, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions II, III, X, XII, XV, and XVI are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The **polypeptide** of Invention II can be used in materially different methods other than to make the antibody of Invention III, the modulator of Invention X, to identify the receptor of Invention XII, to make the computer recordable medium of Invention XV, such as in therapeutic methods. The **polypeptide** of Invention II is independent and distinct from the transgenic animal of Invention XVI because it is not necessary to make or use the polypeptide of Invention II. The **antibody** of Invention III is independent and distinct from the receptor of Invention XII, the computer recordable medium of Invention XV, and the transgenic animal of Invention XVI because none are necessary to make or use the antibody of Invention III. Although the **antibody** of Invention III can be used to obtain the polypeptide of Invention II or the modulator of Invention X, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The **modulator** of Invention X is independent and distinct from the receptor of

Invention XII, the computer recordable medium of Invention XV, and the transgenic animal of Invention XVI because none are necessary to make or use the modulator of Invention X. Although the **modulator** of Invention X can be used with the polypeptide of Invention II or the antibody of Invention III, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The **receptor** of Invention XII is independent and distinct from the modulator of Invention X, the computer recordable medium of Invention XV, and the transgenic animal of Invention XVI because none are necessary to make or use the receptor of Invention XII. Although the **receptor** of Invention XII can be used with the polypeptide of Invention II or the antibody of Invention III, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The **computer readable medium** of Invention XV is independent and distinct from the polypeptide or Invention II, antibody of Invention III, modulator of Invention X, the receptor of Invention XII, and the transgenic animal of Invention XVI because none are necessary to make or use the computer readable medium of Invention XV. The **transgenic animal** of Invention XVI is independent and distinct from the polypeptide or Invention II, antibody of Invention III, modulator of Invention X, the receptor of Invention XII, and the computer readable medium of Invention XV because none are necessary to make or use the transgenic animal of Invention XVI.

5. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Invention II can be made through materially different methods such as chemical synthesis or isolation from natural sources.

6. Inventions I and XVI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the transgenic animal of Invention XVI can be made through materially different methods such as irradiation of embryos or animal husbandry.

7. Each of Inventions IV, V, VI, VII, VIII, and IX and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the modulator of Invention X can be made through materially different methods such as chemical synthesis or isolation from natural sources.

8. Inventions XI and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the receptor of Invention XII can be made through materially different methods such as chemical synthesis or isolation from natural sources.

9. Inventions II and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in materially different process such as biochemical assays.

10. Inventions III and each of I, IV, V, VII, VIII, IX, XI, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each of I, IV, V, VII, VIII, IX, XI, XIII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, V, VII, VIII, IX, XI, XIII, and XIV do not recite the use or production of the antibody of Invention III.

11. Inventions X and each of I, XI, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions X and each of I, XI, XIII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, XI, XIII, and XIV do not recite the use or production of the modulator of Invention X.

12. Inventions XII and each of I, IV, V, VI, VII, VIII, IX, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XII and each of I, IV, V, VI, VII, VIII, IX, XIII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, V, VI, VII, VIII, IX, XIII, and XIV do not recite the use or production of the receptor of Invention XII.

13. Inventions XV and each of I, IV, V, VI, VII, VIII, IX, XI, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XV and each of I, IV, V, VI, VII, VIII, IX, XI, XIII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, V, VI, VII, VIII, IX, XI, XIII, and XIV do not recite the use or production of the computer readable medium of Invention XV.

14. Inventions XVI and each of I, IV, V, VI, VII, VIII, IX, XI, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XVI and each of I, IV, V, VI, VII, VIII, IX, XI, XIII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, V, VI, VII, VIII, IX, XI, XIII, and XIV do not recite the use or production of the transgenic animal of Invention XVI.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth C. Kemmerer

CJN
April 17, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER